

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claim Amendments

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Claims 1, 2, 5, 8 and 9 are currently being amended.

Claim 1 has been amended to recite substituents for L^2 , L^3 and R. Support for the amendment can be found, for example, on pages 8-9 of the Specification. On page 8, line 27 to page 9, line 6 of the Specification, preferred substituents for L^2 and L^3 are disclosed. On page 8, lines 21-23 of the Specification, preferred substituents for R are disclosed.

Claim 2 has been amended to replace “R, R^a , R^1 , R^2 , R^6 , Alk², m and Ar are as defined above and the salts, solvates, hydrates and N-oxides thereof” with definitions for each of the terms. Support for the amendment can be found, for example, on pages 4-5 of the Specification. While page 5, line 15 states “R, R^a , R^1 , R^2 , R^6 , Alk², m and Ar are as defined above and the salts, solvates, hydrates and N-oxides thereof,” page 4, line 6 to page 5, line 10 discloses the definitions for each of the terms.

Claims 5, 8, and 9 have been amended to recite multiple dependent claims in proper format.

No new matter has been added by this Amendment. Applicants reserve the right to file a continuation and/or divisional application to the cancelled subject matter.

After amending the claims as set forth above, Claims 1, 2, 5, and 7-10 are pending in this application. Claims 7-10 are currently withdrawn from consideration.

Rejection under 35 U.S.C. §112, first paragraph

The Office Action has rejected Claims 1, 2, and 5 under 35 U.S.C. §112, first paragraph because the Specification allegedly does not provide enablement for the full scope of all “solvates” of formula I and II compounds.

Without acquiescing, Applicants have amended Claims 1 and 2 to delete the term “solvates” in an effort to expedite prosecution. Accordingly, this rejection is moot. Applicants respectfully request the Office to withdraw the rejection under 35 U.S.C. §112, first paragraph.

Rejections under 35 U.S.C. §112, second paragraph

The Office Action has rejected Claims 1, 2, and 5 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Office Action points out certain terms in the claims that allegedly should be clarified.

The Office Action states that in Claims 1, 2, and 5, the structural elements L² and L³ are not concretely defined. The Office Action suggests that amending the claims so as to incorporate the specific definitions for L² and L³ provided in the Specification, *sans* the language “will include” would overcome this ground of rejection. Applicants appreciate the Office suggesting this amendment.

Accordingly, Claim 1 has been amended to recite, *inter alia*, “in which L² and L³ are independently selected from the group consisting of a covalent bond, a linker atom, and a linker group, wherein the linker atom is selected from -O- and -S-, and the linker group is selected from -C(O)-, -C(O)O-, -OC(O)-, -C(S)-, -S(O)-, -S(O)₂-, -NR¹¹-, -CON(R¹¹)-, -OC(O)N(R¹¹)-, -CSN(R¹¹)-, -N(R¹¹)CO-, -N(R¹¹)C(O)O-, -N(R¹¹)CS-, -S(O)₂N(R¹¹)-, -N(R¹¹)S(O)₂-,

-N(R¹¹)CON(R¹¹), -N(R¹¹)CSN(R¹¹)-, and -N(R¹¹)SO₂N(R¹¹)- groups.” R¹¹ is also defined in the claims as “a hydrogen atom or an optionally substituted alkyl group.” Support for this amendment may be found, for example, on pages 8-9 of the Specification, as suggested in the Office Action.

The Office Action states that the term “substituted” as recited in the claims must be clear and well-defined when read in light of the accompanying specification when the claims themselves do not recite a list of permitted substituents. As Claims 1 and 2 do not recite a list of permitted substituents, the Office Action alleges that the definitions for “substituted” which are provided in the instant specification are not clear most particularly for the reason that they are “circular” in nature.

However, each of the terms recited in Claims 1 and 2 is clear and one of ordinary skill in the art can ascertain the compounds encompassed by Claims 1 and 2. Careful reading of the definitions in the Specification reveal that the definitions indeed can offer guidance to one of ordinary skill in the art to determine the compounds encompassed by the embodiments. For each of the functional groups containing the term “substituted,” there is a limited range in the number of substituents. For example, for “substituted alkyl” on page 24 of the Specification, there is a range of 1 to 5 substituents. While a substituted alkyl can comprise a substituent that is also substituted, one of ordinary skill in the art can determine the compounds encompassed by the embodiments from his knowledge of the art and would not consider utilizing the circular nature of definitions to determine the compounds. Additionally, for functional groups that are substituted, the Specification discloses the identities of the substituents. Thus, the number and identities of substituents on a given “substituted” functional group are disclosed in the Specification. Accordingly, each of the terms recited in Claims 1 and 2 is clear and definite.

The Office Action states that Claim 2 does not include any definitions for the various elements in the depicted molecular structure diagram and instead recites “as defined above,” which is construed to be unclear in the Office Action. Accordingly, Claim 2 has been amended to give definitions for each of the elements in the depicted molecular structure diagram. Support

for the amendment can be found, for example, in the Specification at pages 4-5. At this section of the Specification, definitions for the elements in the depicted molecular structure diagram are disclosed.

The Office Action states that the term “a carboxylic acid or derivative thereof” in Claims 1 and 5 is unclear. As suggested in the Office Action, Claim 1 has been amended to recite, *inter alia*, “R is a carboxylic acid (-CO₂H) group or a derivative thereof selected from lower alkyl ester derivative, a carboxamide group, or an N-lower alkyl carboxamide group.” This amendment finds support in the Specification, for example, at page 8, lines 21-23.

The Office Action states that Claim 5 is included in the rejection because it depends directly from both Claim 1 and 2, thereby incorporating all the limitations of those two claims. Accordingly, Claim 5 has been amended to refer back to Claims 1 and 2 in the alternative with the language “[t]he compound of any of Claims 1 or 2.” Also, Applicants respectfully submit that the amendments and arguments for Claims 1 and 2 overcome the instant rejections and, thus, Claim 5 would also be free of the rejections.

Taken together, Applicants respectfully submit that all of the rejections under Section 112 have been overcome. Reconsideration and withdrawal of same rejections is respectfully requested.

Allowable subject matter

Withdrawn Claims 7-10 are eligible for rejoinder. According to the Office Action, withdrawn Claims 7 and 8 would not present any new patentability issues upon their rejoinder.

Applicants acknowledge the finding of patentable subject matter of Claims 7 and 8.

Request of Rejoinder of Claims 9 and 10

Applicants respectfully submit that Claims 9 and 10 should also be eligible for rejoinder for the same reasons that Claims 7 and 8 are being rejoined. The Office Action affirms the patentable subject matter of Claims 7 and 8. Applicants note that Claims 9 and 10 are directly or indirect dependent on Claim 7. Hence, Claims 9 and 10 would also contain patentable subject matter.

However, the Office Action states that “claims 9 and 10 will be the subject of a rejection under 35 U.S.C. § 112, first paragraph, for lack of a disclosure enabling the practice of the methods specified therein.” Applicants submit that Claims 9 and 10 are supported by enabling disclosure for the recited method, which is a method for treating an inflammatory condition in a mammalian patient.

Page 3 of the Specification states that the claimed compounds are of use in medicine, such as in the prophylaxis and treatment of immune or inflammatory disorders as described in the Specification. Not being bound by the disclosed theory, the Specification at pages 1-3 discloses a correlation between the inhibition of alpha-4 subgroup of integrins and the prevention or treatment of immune and inflammatory diseases. Then the Examples on pages 125-127 of the Specification provide enabling disclosure, such as assays that detect the ability of the claimed compounds to inhibit alpha-4 integrins.

Furthermore, pages 22-24 of the Specification provide how to formulate such compounds into a variety of forms suitable for administration to mammalian subjects and appropriate dosage schedules for such administration. Thus, Claims 9-10 are enabled by the Specification.

Accordingly, Applicants submit that they have provided sufficient guidance to enable persons skilled in the art to use the invention as presently claimed and respectfully request that Claims 7-10 be rejoined.

Conclusion

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

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